



2001 Decisions

Opinions of the United States Court of Appeals for the Third Circuit

8-31-2001

In Re Orthopedic Litigation

Follow this and additional works at: https://digitalcommons.law.villanova.edu/thirdcircuit_2001

Recommended Citation

"In Re Orthopedic Litigation" (2001). *2001 Decisions*. 202.

https://digitalcommons.law.villanova.edu/thirdcircuit_2001/202

This decision is brought to you for free and open access by the Opinions of the United States Court of Appeals for the Third Circuit at Villanova University Charles Widger School of Law Digital Repository. It has been accepted for inclusion in 2001 Decisions by an authorized administrator of Villanova University Charles Widger School of Law Digital Repository.

Filed August 31, 2001

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 00-3899 through 00-3922, 00-3925 through
00-3977, 00-3982 through 00-3984, 00-3986 through
00-4019, 00-4021 through 00-4057, 00-4060 through
00-4095 and 00-4098 through 00-4109

IN RE: ORTHOPEDIC BONE SCREW
PRODUCT LIABILITY LITIGATION

J.T. Bradley and Kathy W. Bradley, Appellants in No.
00-3899

Regina M. Luellen and Eurston Luellen, Sr., Appellants in
No. 00-3900

Randal Jon Uribe, Appellant in No. 00-3901

Mitchell H. Walker and Kim S. Walker, Appellants in No.
00-3902

Jose Morfin, Appellant in No. 00-3903

Mary K. Mullen Schmelter and Kurt Allen Schmelter,
Appellants in No. 00-3904

Rita Jan McGill and Gary McGill, Appellants in No.
00-3905

Louis H. McDowell, Jr. and Patricia McDowell, Appellants
in No. 00-3906

Edward Briscoe, Gloria Briscoe, Dale Lewis Tamborella
and Angela Tamborella, Appellants in No. 00-3907

James E. Doiron and Katherine Doiron, Appellants in No.
00-3908

Jeannette Wade and Edwin Wade, Appellants in No.
00-3909

Leila Hartwell, William J. Hartwell, Jennifer J. Still and Robert Still, Appellants in No. 00-3910

Fitz A. Reid, Etta A. Reid, Lillie Aycock, David Lindsey Brook and Mary Jane Brook, Appellants in No. 00-3911

Gary L. Drake, David Louviere and Laura M. Louviere, Appellants in No. 00-3912

Andrew Jackson Key and Linda C. Key, Appellants in No. 00-3913

Paul David Schneider and Linda Gale Schneider,
Appellants in No. 00-3914

Esperanza Prida and Jorge Prida, Appellants in No. 00-3915

Reyes Basilio and Consolacion Basilio, Appellants in No. 00-3916

Ruth Rogoff, Appellant in No. 00-3917

Juan Perez and Maria I. Perez, Appellants in No. 00-3918

Brian McPherson and Kim McPherson, Appellants in No. 00-3919

Audrey Collins, Appellant in No. 00-3920

Jessie H. Elliott, Jr., Appellant in No. 00-3921

Arvie Jernigan, Appellant in No. 00-3922

Lafiro Max Benavides and Irene Benavides, Appellants in No. 00-3925

John Workman, Appellant in No. 00-3926

Thomas Craig McGowan and Lori L. McGowan, Appellants in No. 00-3927

Max E. Dick, Sr., Appellant in No. 00-3928

Rhonda Renee P. Lawrence and William J. Lawrence, Appellants in No. 00-3929

Raymond C. Cummings and Barbara Ann Cummings,
Appellants in No. 00-3930

Larry Dale Spooner and Terri Spooner, Appellants in No.
00-3931

William P. Arinder, Betty Arinder, Newman Hearn and
Deena Reese, Appellants in No. 00-3932

Randy W. McKenzie and Kimberly Sue McKenzie,
Appellants in No. 00-3933

Karen A. Dunn and Robert T. Dunn, Appellants in No.
00-3934

Bruce Austin and Frances Austin, Appellants in No.
00-3935

Joan Barton and Joseph Barton, Appellants in No.
00-3936

Joseph Collura and Josephine Collura, Appellants in No.
00-3937

Helene Phyllis Cohen, Appellant in No. 00-3938

Joanne Conley Brown, Appellant in No. 00-3939

Connie Ray Baxley, Jr., Angie Baxley, Dick Habour,
Brenda Sue Harbour, Terry Glen Johnson, Sr., Gerald
Dewayne Jones and Sherry Lynn Jones, Appellants in No.
00-3940

Jonathan Bruce Holley, Elise Holley, Jerry Frank Wetz
and Alice Wetz, Appellants in No. 00-3941

Leverne Anthony, Individually, and as Administrator of
the Estate of Joseph Douglas Anthony, Sr., Appellant in
No. 00-3942

Fred B. Basham and Claudia F. Basham, Appellants in
No. 00-3943

Stanley P. Eagle, Sr. and Ladonna M. Eagle, Appellants in
No. 00-3944

Charles E. Porter, Sr., Carol Jourdan Porter, Raymond
Richard and Goldie P. Richard, Appellants in No. 00-3945

Randall L. Metzler, Appellant in No. 00-3946

Lawrence Damion Hickey, Appellant in No. 00-3947

Patricia A. Orlick and Robert Orlick, Appellants in No.
00-3948

Kathy Stockdale and George Stockdale, Appellants in No.
00-3949

Phillip W. Worrell and Janice Ann Worrell, Appellants in
No. 00-3950

John H. O'Connell and Patricia O'Connell, Appellants in
No. 00-3951

Clifford Burt and Barbara Sue Burt, Appellants in No.
00-3952

Chester Allen Morris and Yolan Sybil Morris, Appellants
in No. 00-3953

Salvatore Cali and Genie Cali, Appellants in No. 00-3954

Dean W. Devine and Theresa Devine, Appellants in No.
00-3955

Jason Leigh, Appellant in No. 00-3956

Shirley Baker, Appellant in No. 00-3957

Richard Cullen, Appellant in No. 00-3958

Aline Frances Sears, Albert James Sears, III, John L.
Davis and Louise E. Davis, Appellants in No. 00-3959

Mary Alma Valdez and Alexander Valdez, Appellants in
No. 00-3960

Anthony Wilbur Kyle and Dixie K. Kyle, Appellants in No.
00-3961

Edward Allen, Roxana Paulette Allen, Denise K. Walker,
Allen K. Walker, Annette E. Freeman, Patsy Ruth Elrod
Bell and John Richard Bell, Jr., Appellants in No.
00-3962

Hettie Rovenia Crescini, Benjamin J. Crescini, Sr., James
Fussell, Sherry E. Fussell, Dale C. Hutchinson, Dollinda
Hutchinson, James Paul, Martha Lou Smith Paul, Bobby
Ray Smith, Alvy J. Smith and Martin Carroll, Appellants
in No. 00-3963

Dorris E. Harrell and Margie L. Harrell, Appellants in No.

00-3964

Wesley F. Stokes and Linda Gail Stokes, Appellants in No.
00-3965

Derrill B. Manley and Cindy Manley, Appellants in No.
00-3966

Aubrey J. Ledger, Appellant in No. 00-3967

Edward G. Herrera, Individually and as Administrator of
the Estate of Rosie A. Herrera, Appellant in No. 00-3968

William Daniel Stone, Appellant in No. 00-3969

Jerry Whitaker and Patricia G. Whitaker, Appellants in
No. 00-3970

Rita Gariby and Jesse Rubio Gariby, Appellants in No.
00-3971

Patricia Armijo, Appellant in No. 00-3972

Vera L. Berrington and William J. Berrington, Appellants
in No. 00-3973

Terri H. Gibbs, Arlene F. Parker and William Parker,
Appellants in No. 00-3974

Allen J. Montecino, Jr. and Virginia Montecino, Appellants
in No. 00-3975

Gloria Huntman, Appellant in No. 00-3976

John M. Russo and Karen Russo, Appellants in No.
00-3977

Charles Thomas Wahlquist and Tina Rachelle Wahlquist,
Appellants in No. 00-3982

Sammy Melissa Case and Ronnie Case, Appellants in No.
00-3983

Robert Brozewicz and Denise Brozewicz, Appellants in No.
00-3984

Charles Parrott, Allan R. Whitlow, Dorothy Merle Manberg
and Charles Manberg, Appellants in No. 00-3986

Danny L. Harris, Sr. and Cathie B. Harris, Appellants in
No. 00-3987

Earl Hicks and Debra Hicks, Appellants in No. 00-3988

Amy Foote Weaselbear, Individually and as Administrator
of the Estate of Archie A. Weaselbear, Appellant in No.
00-3990

Laurie L. Coogler, Dennis K. Coogler, Pamela A.
Underferth, Thomas M. Underferth, Billie A.M. King, Cecil
C. King, James Roger Smith and Vermell M. Smith,
Appellants in No. 00-3991

Steve L. Thompson, Appellant in No. 00-3992

Eulalio "Bobby" Adami, Coy R. Griffin, Sr. and Wilma
Griffin, Appellants in No. 00-3993

Ronald Gene Penny and Teresa R. Penny, Appellants in
No. 00-3994

Shirley A. Plott, Appellant in No. 00-3995

Joan McGhee, Appellant in No. 00-3996

Melvin G. Burks, Appellant in No. 00-3997

Michael Seman, Appellant in No. 00-3998

Ginger Bentley and Henry L. Bentley, Appellants in No.
00-3999

Katherine Celia, Appellant in No. 00-4000

Connie Amelia Corley, Appellant in No. 00-4001

Lonnie Lowe, Appellant in No. 00-4002

Robert J. Berglund, Leslie Ann Berglund, Bruce D.
Bultman, Carol Ching Bultman, Gary L. Ewing, Janet
Walker Ewing, Timothy Scott Rushing and Joan Mary
Rushing, Appellants in No. 00-4003

Nancy G. Brown and Ronald E. Brown, Appellants in No.
00-4004

Candace L. Mathes and Stanley M. Mathes, III, Appellants
in No. 00-4005

Kathleen Burke and Earl Burke, Appellants in No.
00-4006

Clifford R. Swain and Savana G. Swain, Appellants in No.

00-4007

James C. Smith and Beverly D. Smith, Appellants in No.
00-4008

Alex A. Driggers and Margie Ann Driggers, Appellants in
No. 00-4009

Isidora Fuselier, Albert J. Fuselier, Michael Lee Andrus
and Mark A. Bullard, Appellants in No. 00-4010

Harry Alan Bowser and Ronda L. Bowser, Appellants in
No. 00-4011

Michael D. Holloway, Appellant in No. 00-4012

Lillian Marchegianni and John Marchegianni, Appellants
in No. 00-4013

Jerry DeWayne Harrison and Mary M. Harrison,
Appellants in No. 00-4014

M. Mary Coleman, Appellant in No. 00-4015

Jessie Flores and Mary I. Frias Flores, Appellants in No.
00-4016

Kap Jong Lee and Sung Wan Lee, Appellants in No.
00-4017

Richard Fontenot, Peggy Sue Fontenot and Perry Bang,
Appellants in No. 00-4018

Wallace Wade Prahser and Donna Prahser, Appellants in
No. 00-4019

James W. Ervin, Jr., Appellant in No. 00-4021

Larry Hugh Gibson and Connie Marine Gibson, Appellants
in No. 00-4022

Leonard Otis Smith and Hazel M. Smith, Appellants in
No. 00-4023

J.P. Parker, Appellant in No. 00-4024

Bruce W. Shepherd and Lorene B. Shepherd, Appellants
in No. 00-4025

James Toskes, Appellant in No. 00-4026

Priscilla Fontenot, Lester Joseph Fontenot, Lee Anna Scott, Arthur Scott, Jr., John Goodman, Gertrude Goodman, Janice Reed, David Reed, Deidre Guillory, Barbara L. Comeaux and Leander Comeaux, Appellants in No. 00-4027

Marilyn A. Greiner and Emil D. Greiner, Appellants in No. 00-4028

Jamie Lee Samuels and Thad J. Samuels, Appellants in No. 00-4029

Merle L. Jensen, David Bernard Jensen and David Rounkles, Appellants in No. 00-4030

Melissa Ann Chandler, Appellant in No. 00-4031

Thomas Levon Jones and Beverly Jones, Appellants in No. 00-4032

Irene Portillo, Appellant in No. 00-4033

Theodore N. Helton and Josephine T. Helton, Appellants in No. 00-4034

Grant Edward Tingstrom, Cathy J. Carrick, David L. Carrick, Sr., John Shaver and Diana Shaver, Appellants in No. 00-4035

William D. Sipes and Thelma G. Sipes, Appellants in No. 00-4036

George Love and Rosemary Love, Appellants in No. 00-4037

Joseph Anthony Strange, Appellant in No. 00-4038

Frank L. Bowes and Lollie Bowes, Appellants in No. 00-4039

Bruce Anthony Davis and Mary Ann Davis, Appellants in No. 00-4040

Gaty M. Jones and Janice A. Jones, Appellants in No. 00-4041

Elizabeth Bablitz and August E. Bablitz, Appellants in No. 00-4042

Caridad Perez, Rogelio Perez, Michael Joseph Smith, Rebecca A. Smith and Maria C.P. Bezara, Appellants in

No. 00-4043

Vall R. Williams and Zolla Williams, Appellants in No.
00-4044

Kimberly DeRose, Michael J. DeRose, Salvatore Babriale,
Jr. and Sandee Gabriele, Appellants in No. 00-4045

Billy Hines and Brenda Hines, Appellants in No. 00-4046

Michael Scott Schirmer and Patsy Schirmer, Appellants in
No. 00-4047

Denis Ray Dunlap, Bernadette Dunlap, George R. Wiley,
Judy Mize Wiley, Jeffery Lynn Miller and Donna Miller,
Appellants in No. 00-4048

Cynthia Jo Lackey and Joseph Lackey, Appellants in No.
00-4049

Marsha Stites, Appellant in No. 00-4050

James Joseph Morway and Kristie Jo Morway, Appellants
in No. 00-4051

Sandy Price and Michael L. Price, Appellants in No.
00-4052

Robert Shehan and Cleta Shehan, Appellants in No.
00-4053

Theresa L. Fitzgerald and John Patrick Fitzgerald, Jr.,
Appellants in No. 00-4054

William G. Warthen, Appellant in No. 00-4055

Roy H. Dedman, Nicole Dedman, David P. Abeyta and
Lorri S. Abeyta, Appellants in No. 00-4056

Carroll D. Harris and Sharon Kay Harris, Appellants in
No. 00-4057

Jerry Dale Arnold, Bonnie Sue Arnold and Elizabeth
Cullen Ohrum, Appellants in No. 00-4060

Jackie C. Crenshaw and Rosetta A. Crenshaw, Appellants
in No. 00-4061

Linda Patten Hitchcock and Dennis A. Hitchcock,
Appellants in No. 00-4062

Frans R. Dorris and Dianne Reichenbacher-Dorris,
Appellants in No. 00-4063

James Stroderd and Paula Stroderd, Appellants in No.
00-4064

Kathy Diane Young and Billy Dale Young, Appellants in
No. 00-4065

Gregory H. Hardin, Appellant in No. 00-4066

Raymond Nolan, Jr., Appellant in No. 00-4067

Michael Galloway and Pat Galloway, Appellants in No.
00-4068

Frank L. Dachenhausen and Thelma I.F. Dachenhausen,
Appellants in No. 00-4069

Carmine A. Cilella and Gabriella Cilella, Appellants in No.
00-4070

Ronald Leroy Lee, Linda Lee Castleberry and H.L.
Castleberry, Appellants in No. 00-4071

David Onger, Appellant in No. 00-4072

James T. Livingston, Jacqueline A. Livingston, Ronald
Wayne Dean, Nanni P. Dean, William E. Boyer, Sr, and
Melanie Kay Boyer, Appellants in No. 00-4073

Kenneth Kulhanek, Appellant in No. 00-4074

Rosemary K. Barotti, Peter W. Barotti, Kathryn McBratney
and Jeff McBratney, Appellants in No. 00-4075

Billy Holbrook and Sherrie Holbrook, Appellants in No.
00-4076

Robert Geib and Donna Marie Geib, Appellants in No.
00-4077

Joyce Ann Robichaud, As Administrator of the Estate of
Ray Robichaud, Appellant in No. 00-4078

Jimmy Shoemaker and Annette Shoemaker, Appellants in
No. 00-4079

Jose Luis Rivera, Concepcion Rivera, Roslyn Del Pradia
Wilson and Henry E. Wilson, Sr., Appellants in No.

00-4080

Bertha A. Salazar Vasquez and Hector G. Vasquez,
Appellant in No. 00-4081

Donald Lynn McKeown and Janice McKeown, Appellants
in No. 00-4082

Pauline Strickland White and Henry Willis White,
Appellants in No. 00-4083

Jerry Dale Lewis and Mary D. Lewis, Appellants in No.
00-4084

Opal A. Parham, Appellant in No. 00-4085

Hazel Dueitt Sweatt and Earl Lynn Sweatt, Appellants in
No. 00-4086

Marilyn Fitzgerald, Appellant in No. 00-4087

Alice McKinnon Clayton, Appellant in No. 00-4088

Maria De La Cruz and Miguel Angel De La Cruz,
Appellants in No. 00-4089

Barbara Ann Bruzer and Dale Eugene Bruzer, Appellants
in No. 00-4090

Joseph Lee Castle and Sandra Collins Castle, Appellants
in No. 00-4091

Patricia Ann Hill and William A. Hill, Appellants in No.
00-4092

Annie Ruth Fralick, Appellant in No. 00-4093

Thomas James Olsen and Gloria M. Olsen, Appellants in
No. 00-4094

Linda Newberry and Dave Newberry, Appellants in No.
00-4095

Estate/Heirs of Sharon Alderman*, Estate/Heirs of Ralph
C. Anderson*, Todd Anselmo, Judith E. Anselmo, Phil
Barber, Janice M. Barmore, Julie P. Barrack, Daniel W.
Bartelt, Robert E. Bennett, Lois K. Bergsjo, Andrew L.
Barry, Rebecca J. Boe, Clairce E. Boggs, Barbara Kay
Bremer, Pamela M. Brewster, Morton G. Brill, Lenore
Brill, Alonzo Brown, Vicki J. Brusewitz, James Buresh,

Betty Butler, John Butler, Arlene V. Carlson, Diane L. Cassidy, Dennis Cassidy, Julie A. Charette, Dale Charette, Brian K. Ciske, Denise Cook, Muriel A. Crowley, Lillie M. Dabney, Timothy J. Dickau, James Douglas, Cheryl M. Douglas, Leona S. Ehnert, Majorie A. Etzel, Daniel M. Etzel, Cary M. Femrite, Robert L. Fields, Elizabeth A. Fischman, Donald J. Flower, Scott Fullex, Dennis J. Gallagher, Michael A. George, Calvin W. Gilbo, Sr., Donna C. Green, Sharon L. Griffin, Eloy Guzman, Sr.*, Roberta E. Hammerlind, Patricia L. Heidelberger, Raymond C. Hermanson, Gail Hermanson, Mark W. Herrman, Cynthia Herrman, Judith I. Hughes, Reginald F. Hughley, Todd W. Illies, Michael W. Iverson, Gayle E. Johnson, Dale Johnson, Janice M. Johnson, Daniel Johnson, Peter H. Johnson, Peggy Johnson, Cindy Osborne Keim, Barbara A. Kern, Karen M. Klein, Katherine E. Koehler, Barbara J. Kunshier, Robert B. Kwasigroch, Estate/Heirs of Robert A. Laessig*, Estate/Heirs of Frances Laessig*, David G. Lewandowski, Donnie K. Lilly, Donald J. Lisk, Patricia A. Lilly, Nancy L. Lisk, Craig W. Locher, Jodi Locher, Patricia J. Mandli, Michael M. Martinson, Anthony Martorana, Jean J. Martorana, Lorraine B. Mathis, Ethel McClain, Michael R. McConnell, Donald R. McRae, Jacqueline E. McRae, Virginia A. McVicker, William McVicker, Wendell D. Meeker, Marjorie L. Melinski, Shirley A. Moen, Marcy Myers, Jean A. Ness, James Ness, Jack C. Nicholson, Kathleen L. Nicholson, Cheryl M. Novotny, Richard A. Novotny, Larry J. Novotny, Claudette M. Novotny, Dennis W. Olson, Margery Olson, Ronald W. Olson, Randy R. Otto, Joan A. Pasowicz, Joseph Pasowicz, Stephen E. Paxton, Lisa M. Lugo-Paxton, Frederick L. Peck, Tina J. Peck, Estate/Heirs of George J. Pesek*, Estate/Heirs of Katherine H. Pesek*, Estate/Heirs of Eugene S. Prantner*, William Peters, Lucille L. Peterson, Suzanne R. Petrusic, Walter Petrusic, Robert J. Plaksy*, Sharon Plaksy*, Ratsy Rathke, Arlene E. Reed, Ronald Reed, Rick Reizer, Jeffrey Richie, Debra A. Richie, Ricky K. Romaine, Lloyd Rose, Larry S. Rudolph, Lee R. Rysdam, Marija Rysdam, Richard H. Salverda, Rosemary Schibley, Phillip E. Schmidt, Margaret A. Schmidt, Jeanne E. Skarda, Raymond T. Sobotta, Lee A. Solomon, Michael J. Spartz, Glee H. Spartz, Steven G. Starker, Edward J. Tentis,

Gerard A. Theis, George E. Toth, Barbara Toth, Victor Towler, Barbara J. Venne, Mary Weinstein*, Milo D. White, Stefanja Z. Wojtczak, Jay H. Wyttehoeve and John W. Zink, Sr., Appellants in No. 00-4098
(*Caption amended per Court's Order dated 8/27/01)

James D. Bitzer, Charity A. Bitzer, James A. Mortensen, Dennis Raymond, Marlene Raymond and Mary L. Yeager, Appellants in No. 00-4099

Douglas J. Callaway, Dana Callaway, Ronald R. Sivak, Ann M. Weiler and Norbert Weiler, Appellants in No. 00-4100

Richard E. Almquist, Patricia E. Almquist, Kathie L. Avery*, Charles W. Avery, Gerald T. Baron, Margaret L. Bennett, Geneva G. Bissonette, William D. Bolton, Jr., Joan Bolton, Jeanne A. Borkowicz, Ronald J. Borkowicz, Mark A. Chapman, Arthur L. Cotter, Barbara A. Cotter, Lynda M. Dahl-Kocurek, Silviu Dan*, Estate/Heirs of James Domaszek*, George I. Florek, Jeanne Florek, Debra G. Fox, Joseph Fox, Herman Haayer, Jr., Pamela Haayer, Darlene D. Halder, Robert A. Hayes, Leah J. Henkel, Donald E. Hereau, Dorothy J. Hereau, Steve C. Hesse*, Nancy Hesse*, Estate/Heirs of Judy Jolly*, Wayne Jolly*, Michael J. Kaiser, Jody A. Lagergren, Todd Lagergren, Lois J. Lenzo, Gale R. Mattison, Ruby R. Pabelick, Michael D. Platts, Kathy Platts, Richard A. Pynenberg, Donna Rau, Glenn Rau, Judith G. Richart, Robert Richart, Jeffrey Richie, Debra A. Richie, Robert L. Schmalfeldt, Lori J. Schmalfeldt, Lonnie C. Shelley, Sharon Shelley, Sharon L. Swanson, Joan M. Valenty, Mary L. Yeager and Charles A. Zinn, Appellants in No. 00-4101
(*Caption amended per Court's Order dated 8/27/01)

Michael K. Bentley, Marlene E. Bergeron, Joyce A. Bushrod, Robert R. Burns, Hanna Cahsai, Gail R. Copeland, Faye R. Copeland, Denise Cook, Lillie M. Dabney, Becky L. Dykes, Jerome T. Engel, Robert L. Fields, Mark D. Frakes, Gina Frakes, George C. Gonzalez, Brenda Gonzalez, William A. Green, Martha J. Green, Lois A. Hartwig, David L. Hartwig, Charles W. Hughes, Deane M. Hughes, Robert J. Johnson, Joan Johnson, Eileen E.

Kaiser, Cindy Osborne Keim, Allen Kline, Jeffrey A. Koch,
Laura J. Kollmer, Chris J. Kollmer, Michael A. Lachapelle,
Donald J. Lisk, Nancy L. Lisk, Mitchell Pezanoski, Mary
Pezanoski, Kenneth E. Retkowski, Gayle Retkowski,
Joseph P. Schoenborn, Dawn J. Shelton, Darryl C.
Shelton, Michael J. Spartz, Glee H. Spartz, Steven G.
Starker, Danette T. Tellijohn, Richard A. Theisen, Michael
Thompson, Victor Towler, Timothy P. Tucker, Mary
Weinstein*, Theresa Bichler Wichman and Mark J.
Wietzke, Appellants in No. 00-4102
(*Caption amended per Court's Order dated 8/27/01)

Holly Bair*, Walter Austin, Hubert W. Bellisle, Mary J.
Bellisle, Andrew L. Berry, Marlene M. Biggins, Thomas
Biggins, James J. Breen*, Thelma Breen*, Estate/Heirs of
Robert J. Brown*, Vivian Brown, Karen R. Callahan,
Cathleen A. Crandall, Albert A. DiCruttalo, III, John
Doherty, Robert C. Duisen, Jr., Carla J. Ford, Dana W.
Frank, Joann C. Frank, John C. Frank, Gail R. Frank,
Estella Gamez, Linda S. Gipson, Donald F. Goold, Joan
M. Goold, Mitchell E. Grav, Carolyn M. Hendley, Theron
Hendley, Timothy Hill, Patricia F. Kearns, Dorothy M.
Kinn, Florence I. (Wong) Lakin, Valerie E. Lennon, Jack
W. McGillivray, Beatrice McGillivray, Kurt R. Meintsma,
Brenda L. Moorer, Tillman E. Olson*, Victoria M. Olson,
Ruth H. Perkel, Malcolm Perry, Monica Perry, Jack
Robinson, Gregory Rubbo, George N. Ruzynski, June
Ruzynski, Anna M. Scully, Lee A. Scully, Scott Silva,
Michael J. Spartz, Glee H. Spartz, Steven Staudt, Tracy
Staudt, Allen R. Terry, A. Thorne, Sandy Thorne, Victoria
L. Valente, Ralph Abagian, Judy M. Walker, Estate/Heirs
of Gerald F. Wehler*, Marjorie Wehler, Frank J. Williams
and Angie Williams, Appellants in No. 00-4103
(*Caption amended per Court's Order dated 8/27/01)

Christine M. Anderson, Oscar Bernal, Gail R. Copeland,
Faye R. Copeland, Steve Ferguson, Cindy Osborne Keim,
Robert LaBlanc, Melvin Martin, Brooke Meyers, Riley L.
Norris, Joyce Norris, Daniel P. Monson, Janet Smith, Bob
Smith, William J. Vlasek, Doris Vlasek, William
Walkenbach, Paul B. Wall, Sandra Weaver and Judy M.
Walker, Appellants in No. 00-4104

James D. Ash, Cynthia Ash, Estate/Heirs of Sharon
Alderman*, James R. Ashley, Mary A. Aune, Holly Bair*,

Edward Barnes, Donald L. Beckman, Debra S. Beckman,
Emma L. Bennike, Robert E. Bennett, Nancy L. Brett,
Gregory Brett, Joyce A. Bushrod, Karen R. Callahan, Traci
W. Chapman, Gail A. Christian, Dorsey W. Cole, Carla J.
Colombo, Belinda M. Cook, Scott M. Daniels, Robert C.
Degeest, Thomas K. Dillon, Jeanne M. Garchek, Cecil P.
Gibby, Betty Gibby, Carolyn Gibson, Raymond A. Golden,
Estate/Heirs of Essie L. Goldsmith*, William A. Green,
Martha J. Green, Bobby Harrison, Everett E. Hendrickson,
Pat Hendrickson, Joan C. Hochbrunn, Thomas
Hochbrunn, Bertha E. Hokkanen, John Hokkanen, Julie
A. Hunt, Renee M. Janusz, Mary L. Johnson, Alan K.
Johnson, Thomas W. Keene, Rosalie G. Keene, Nancy J.
Kellam, James Kellam, Paul W. Kelly, Gerald J. Kernan,
Jeffrey A. Koch, Benjamin F. Korfe, John A. Kraus, Jr.,
Karen J. Lyons, Donald Lyons, Jr., Estate/Heirs of Mae
V. Martin*, Calvin Martin, Melvin Martin, Gary P.
McFarland, Jody McFarland, Alan R. McGee, Virginia A.
McVicker, William McVicker, Robert Mertens, Brooke
Meyers, Catherine J. Muha, Harold Mulcare, Randy A.
Murray, Tracy Murray, Maxine T. Narog, Steve R.
Newman, Linda Newman, Randy R. Otto, Freddie L.
Owens, Paulina Pappas, John R. Pappas, Kay Parr, James
H. Parsons, Janet S. Parsons, Estate/Heirs of Norman
Persten*, Richard J. Pietrzak, Karla Pietrzak, Frances H.
Popham, Ronald Richards, Wayne W. Richards, Debra
Richards, Kathleen Richardson, Luis Rivera, Roland C.
Roberts, Patricia Roberts, Rose M. Robinson, James F.
Robinson, Michael S. Ryan, John C. Salas, Howard D.
Sams, Marion A. Sams, David R. Scalise, Clarence I.
Seaburg, Joseph A. Sherry, William J. Skobjak, Annette
Skobjak, Beulah E. Skoog, Lee A. Solomon, David J.
Stanoch, Denise A. Stanoch, Marlette C. Steinke, Kathryn
L. Stout, Denzil L. Stout, Michael D. Supple, Mary B.
Supple, Danette T. Tellijohn, Gerrye W. Tippens, Jerry
Tippens, Albert E. Topolski, Brian Vaughn, Tom E.
Wadsworth, Estate/Heirs of Gerald F. Wehler*, Marjorie
Wehler and Roberta Zimmerman, Appellants in No.
00-4105
(*Caption amended per Court's Order dated 8/27/01)

Donald Lombard, William C. McPhail and Estate/Heirs of
Charles D. Reynolds*, Appellants in No. 00-4106
(*Caption amended per Court's Order dated 8/27/01)

Joanne Benton, Michael Sita, Beverly Sita, Gregory
Osburn, Joy Osburn, Kelly D. Cowan, James Smith, Judy
Smith, John Horton, Sandra Horton, Geraldo Feregrino,
Laura Feregrino, Phillis Driver, Julian Whitten, Debra
Whitten, Deva Buttram, Edward Buttram, Henry J. Klein,
Patricia LaBree, Amos Jenkins, Linda Jenkins, James H.
Reske, Sr., Ned Johnson, Maxine Johnson, Paula
Watkins, Eyssel Gurganus, Henry Gurganus, Victoria B.
Jones, Kirby Tharrington, Betty M. Brantley, Phyllis Perry,
Claude Perry, Mary Thatch, John Thatch, Leotha Forte,
Phyllis Forte, Emily Ennis, Lilyn D. Taux, Dilcy L. Hall,
Carlton Parris, Joseph Amos, Christopher Poole, Missouri
Garner, Victor Garner and Cynthia Esposito, Appellants in
No. 00-4107

Donna Marie Beauchemin, Aaron Wayne Calk, Debra
Calk, Vincent Foster Cochran, Peggy Joyce Cochran, Mary
N. Hix, John M. Hix, Nicholas Host, Debra Ann Host,
David S. Lambert, Donnalyn Acosta, Robert E. Lee, Kathi
Lewis, Shirley Lewis, Roger W. Lovell, Brenda Kay Graves
Lovell, Gilbert Martinez, Jr., Maria Martinez, Ralph M.
Nielsen, Marie J. Nielsen, David Perry, Brian Quinn,
Cheryl Ann Smith, Donald Smith, David L. Spottek,
James Swisher, Richard Lynn Thornton, Paul Williams,
Barbara Jean Wilson, B.E. Wilson, Catherine A. Wright,
Michael A. Bloomfield, Leslie J. Bloomfield, Kathleen
Burke and Earl Burke, Appellants in 00-4108

Sherry Adams, Daniel Ray Adams, Betty C. Alisouskas,
Vincent F. Alisouskas, Dwayne Junior Allen, Doyleene
Todd Allen, Richard Lee Allen, John D. Austin, Tami
Austin, Robert Lee Baker, Cecil W. Barnett, Glenda Mae
Harper Barnett, Vivian K. Basham, Arice M. Basham,
Lucy Frances Bauman, Thomas Richard Bauman, Sr.,
Michael Belliveau, Lisa Belliveau, David Benavidez, Teresa
Garcia Benavidez, Betty Jean Bennett, Betty Joanne
Benning, Anthony P. Bertrand, Evelyn Sue Bertrand,
James Charles Besch, Bernice Ann Lay Besch, Deborah
Best, Joseph C. Best, Ronald Coburn Billings, Tina Marie

Billings, Patricia Ann Blackledge, Buddy W. Blackledge,
 Sr., John William Blasko, Daniel L. Blemke, Beulah A.
 Boatsman, Stanley Dale Boogs, Linda Carolyn Latham
 Boggs, Lynn H. Boles, Juanita Frogge Boles, Aulpheda
 Bonner, Jimmy T. Bonner, Melton Jack Book, Charlotte
 Book, Dennis P. Borghesi, Gayle Borghesi, Dorothy H.
 Bower, Marvin Lee Bower, Lora A. Bower, Bonnie F.S.
 Brinegar, Rocio Mier Brodd, Wayne M. Brodd, Agnes Jean
 Brothers, William L. Brothers, Marvin J. Brouillette, Sr.,
 Mary Lois Brouillette, Edgar Steve Brown, Tina R. Miers
 Brown, Lynn Jimette Brown, Michael Lynn Brown,
 Leonard Bushnell, Katherine Bushnell, Larry G. Carlson,
 Pamela G. Carlson, Luis H.G. Casanas, Arvie L. Causey,
 Doyle E. Chamblee, Hilda M. Chamblee, James H.
 Chambless, Richard D. Chandler, Stephanie W. Chandler,
 Vyron Breen Cherry, Dana Delores Marvin Cherry, James
 L. Christina, Susan Y. Christina, Ethel Coffman, Dennis
 D. Compton, Jerri Sue Compton, Harry C. Conner, Sr.,
 Melina J. Conner, Randall C. Corbello, Rita M. Corbello,
 James Cottrell, Lois Couvillion, Estine Covillion, Peter L.
 Covert, Susan K. Covert, Rodger K. Cox, Edith Mills-Cox,
 Jack Craycraft, Phyllis Craycraft, Timothy Cunningham,
 Jennifer Cunningham, Richard Daniel, Debra J. Daniel,
 Mark Dixon DeHaven, Robin Lynn DeHaven, Lou Ella
 DeVille, Ty Dwayne Dick, Audrey Ann Dick, Sally M.A.
 Dickinson, Richard Dickinson, James Doherty, Shirley L.
 Dollarhide, Gerald J. Dollarhide, Marion Domer, Valerie
 Domer, Janice Miller Dowdy, William E. Dowdy, Richard
 Drumheller, Patricia Ann Crane Dulny, Roberta N. Dunn,
 Eugene D. Dunn, Jr., Lisa Hoens Guest DuPont-Aguillard,
 Joseph M. DuPont, Russell G. Einolander, Phyllis Lynne
 Elliott, Randall C. Elliott, Roger Keith Emrick, Penny Jae
 Emrick, Judy Evans, Howard L. Evans, Fred Preston Cone
 Evatt, Sr., Trubee Laverne Evatt, Edith G. Fewell, John
 Thomas Fewell, Robert J. Firek, Kathleen Mary Firek,
 Mary Frances Flory, Theresa M. Foltz, Louis Foltz, George
 M. Fontenot, Juanita C. Fontenot, Wilbert Fontenot, Reata
 Fontenot, Selby Clyde Ford, Dorothy C. Ford, Cynthia
 A.O. Foxworth, Debbie Fredette, Ernest A. Freeman, Ellen
 R. Fretty, Earl J. Fruge', Susan Fruge', Mark D. Fuller,
 Rosalva Fuller, George E. Garcia, Sally A. Garcia, Maxine
 Joan Gardetto, David T. Gardner, Leo Gardner, Jr.,

Beverly Sue Gardner, Gertrude Gautreaux, Kimberlee Gavosto, Darrin Gavosto, Murry C. Gear, Claretta I. Getts Gear, Greg Gillum, Jr., Ruth A. Gillum, Marietta L. Gjertsen, Brian Todd Glowka, Kristi L. Glowka, Patricia Grant, Forrest Griffin, Judith A. Potthast Griffin, Eva Grimes, Jerry Grimes, John S. Hallmark, Sr., Wanda J. Michaels-Hallmaker, Mark E. Hanson, Brenda Hanson, David Earl Hardy, Gloria D. Brooks Hardy, Louis Edward Hatsfelt, Sr., William Hayes, Linda E. Hayes, Patricia Henderson, Frank L. Herron, Cassandra Herron, Marie Black Hinson, Robert Steven Hinson, Nelson Hoffpauir, Rose Marie Holder, Timothy L. Hurd, Brenda Hurd, Lanny Jackson, Dora Ann Jackson, Joseph J. Jarmasek, Sr., Barbara Jarmasek, Walter Jeane, Mary H. Jeane, Carol Elaine Jewitt, Michael H.A. Jewitt, Edward Grant Johnson, Hazel Ross Johnson, L.C. Johnson, Dixie Brannon Johnson, Edna Lee Jones, Merleyn C. Jones, Victor L. Jones, Sharon Jones, Earl Jordy, Jr., Anita Jordy, Robert Kaminski, Linda Kaminski, Richard D. Kidd, Marlene Kidd, Thomas V. Kilgore, Penny Kilgore-Thomas, Barbara L. King, Deryl D. King, Victor Clyde Knapp, Jr., Deborah Kay Knapp, George Alvin Knight, Linda Sue Knight, Mary Kroupa-Casey, Kevin P. Casey, Andrew D. Kubiczki, Mary Kubiczki, Joanne L. Kuci, Feta Hysen Kuci, James A. Kuhns, Clay Carlton Kutscher, Helen Lamontagne-Eddy, Leona Lapradd, Ronald D. Larabee, Peggy Larson, Everett Larson, Patsy A. Lehmann, Paul Alton Livingston, Darrell W. Logan, Rebecca Logan, Sylvia G. Loucks, John Foster Loy, James E. Malenfant, Suzanne M. Malenfant, Zetty Malone, John F. Manley, Carlene E. Mansfield, Richard Marble, Inda Marble, Gary M. Marks, Clara D. Marrs, Gordon Ray Marrs, Debra K. Martin, Lyle E. Martin, Sandra Mason, Floyd Mason, Jacqueline B. Mauldin, Arthur Lewis Mauldin, William Lee McDuell, Birdie J. McDuell, Kevin L. McGaw, Becky Anderson, Arthur James McHugh, Mary Ann McHugh, Tony McKnight, Alex Mercado, Joann Mercado, Rachel Miller, Anthony Miranda, James Felton Mitcham, Lynn Mitcham, Evelyn Marie Mitchon, Kenneth H. Moore, Linda A. Moore, Ronnie Moore, Marva Moore, Myra Helen Moreau, J.R. Moreau, Kathleen H. Morris, Richard Morris, Donald Bruce Mountjoy, Kathleen

Connor, Paul Mouton, Patricia M. Mouton, Katheryn D. Mueller, Allan G. Mueller, James Murphy, Beverly Blassingame Murphy, Robert E. Murphy, Bonnie Murphy, Kimberly Naglich, Mark T. Naglich, Steve A. Nave, Katherine L. Nave, Jerry W. Newman, Mary Newman, Max H. Nix, Marilyn Joyce Nix, Brigitte H. Noorlander, John A. Noorlander, George E. O'Bryant, Alice Lightly O'Bryant, Richard S. Parker, Sylvia Inez Parker, Bobby Pelfrey, Stanley Perlstein, Gerald W. Pettifield, Ronald Plesz, Velda B. Plesz, Carolyn Rene Posey-Bond, Robert Clayton Bond, Michael G. Queen, Janice G. Queen, Kenneth P. Rainwater, Darlene S. Rainwater, Vicki Diana Jarrell Ramey, Richard Dale Ramey, Janet Ranney, Donald H. Ranney, Deborah Dee Reimund, Terry Allen Reimund, Sheri Lynn Revers, James Revers, Sharon Rewis, John Rewis, Jr., Shelia A.H. Rinehart, Ellis W. Rinehart, Danny Lee Ringo, Debra Ringo, Joan K. Roberts, Tommy L. Roberts, Patricia Ann Roberts, Dexter Robinson, David L. Ross, Carol Ross, John Ryan, Lawrence W. Salminen, Teddy Salmon, Anita Joy Salmon, Keith Watson Sandeford, Donna Baird Sandeford, Michael J. Schlaikjer, Christina Lynn Schlaikjer, Carlton William Schmidt, Peggy R.U. Schrier, Marylyn Ann Schultz, Roy Schultz, Leo G. Scott, Sheila G. Scott, Louis Servin, Donna Servin, Steven R. Shafer, Janice Shafer, Jane L. Shoe, Mary Ann Shores, James B. Shores, Tommie C. Shoulders, Lorraine Shoulders, Elton Son Shults, Thomas Dudley Sides, Rosa F. Silva, Heriberto Silva, Martin Simmons, Diane Dille-Simmons, William B. Skelton, Sr., Agnes Lucille Skelton, Darrell Slape, Miriam P. Slavich, Ivan L. Slavich, Alfred Andrew Smith, Martha Jane Smith, George Smith, Elizabeth F. Smith, James Roger Smith, Vermell McBride Smith, Terry Eugene Smith, Penny Talley Smith, Kevin G. Spencer, Nikki Spencer, Charles F. Stacks, Sarah Jan Stacks, Jerry Stephenson, Brenda J. Stinson, Max E. Stinson, Paul H. Stockton, Nancy E. Stockton, Margie A.B. Stone, Vernon Odell Stone, Richard W. Stull, Donna Wojtasinski Stull, William P. Sturgeon, Audrey M. Tallant, Roger Dennis Watkins, John Tarka, Lorriane A. Tarka, Michael Franklin Taylor, Denise King Taylor, Nicholas Tentzeras, Dwight H. Terrell, Billy P. Thaggard, Linda Thaggard, Frances E. Thibodeau, Larry Thomas, Annette

Marie Thomas, James F. Thomason, Mark A. Thornton,
Donna L. Bonin Thornton, Terina Smith Threadgill, Larry
E. Threadgill, Jr., James E. Timberlin, Sr., Frank E.
Tomlinson, Donna Elizabeth Tomlinson, Diane Elaine
Tresfon, Dewey Ronald Tubb, Charlotte P. Tubb, Richard
C. Tucker, Deborah S.B. Turner, Harry D. Turner,
Virginia F. Turner, Wendell Turner, Sr., Brian P.
Vannatta, Charles P. Votruba, Denise C. Votruba,
Kenneth Wade, Dianna Wade, James C. Walston, Sr.,
Ethel Marie Walston, James A. Ward, Kathleen Ward,
Sharon R. Ward, Bruce L. Ward, John Layton Webb,
Clark Welcher, Sharyl Welcher, Marie D. White, James S.
White, Donald Edward Wilder, Betty Jane Murray Wilder,
Cecil Williams, Jane Watson Williams, M. Teresa Willis,
Larry N. Wilson, Octavia Wilson, Stephen W. Wilson, Lisa
Wilson, William C. Winders, Virginia Winders, Rondell
Vernon Wood, Dolores Laverne Wood, Tracy L. Workman,
Janine Lee Workman, Kristine E. Young, Charles Drake,
Priscilla Fontenot, Lester Joseph Fontenot, Thomas C.
McGowan and Lori L. McGowan, Appellants in No.
00-4109

On Appeal From the United States District Court
For the Eastern District of Pennsylvania
(MDL No. 1014)
District Judge: Honorable Louis C. Bechtle

Argued: June 28, 2001

Before: BECKER, Chief Judge, NYGAARD and
REAVLEY,* Circuit Judges.

(Filed August 31, 2001)

* Honorable Thomas M. Reavley, United States Circuit Judge for the Fifth
Circuit, sitting by designation.

John J. Cummings, III, Esquire
Frank C. Dudenhefer, Esquire
(Argued)
Cummings, Cummings, &
Dudenhefer, A.P.L.C.
416 Gravier Street
New Orleans, LA 70130

Karen Cody-Hopkins, Esquire
Ronald S. Goldser, Esquire
Zimmerman, Reed, P.L.L.P.
901 North Third Street, Suite 100
Minneapolis, MN 55401

David A. Vesel, Esquire
Law Offices of David A.
Vessel, P.A.
8212 Creedmoor Road,
Suite 101
Raleigh, NC 27613

Counsel For Appellants

Stuart E. Schiffer, Esquire
Acting Assistant Attorney General

Michael Levy, Esquire
United States Attorney
Eastern District of Pennsylvania

Mark B. Stern, Esquire
Charles W. Scarborough, Esquire
(Argued)
Attorneys, Appellate Staff
Civil Division, Room 9611
U.S. Department of Justice
601 D Street, NW
Washington, DC 20530-0001

Margaret Jane Porter, Esquire
Chief Counsel
Patricia J. Kaeding, Esquire
Associate Chief Counsel
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Counsel For Appellee

OPINION OF THE COURT

REAVLEY, Circuit Judge.

This Federal Torts Claims Act (FTCA) claim against the Food and Drug Administration (FDA) for granting clearance to market certain types of pedicle screw fixation devices (referred to generally as bone screws) was dismissed by the District Court pursuant to the discretionary function exception to the FTCA.¹ Appellants contend here that this jurisdictional exception should not apply because FDA officials were guilty of misconduct in the process of granting the clearance, and because Appellants should have been given more opportunity to discover proof of that misconduct. Moreover, Appellants argue that, even if the discretionary function exception does apply to the aspect of the bone screw clearance process challenged in their suit--i.e., the clearance of bone screws based on their substantial equivalence to devices already on the market--the exception does not bar Appellants' claims because the FDA's substantial equivalence determination does not involve the requisite element of judgment and choice, and is not the type of policy-based decision that the exception is designed to protect. Because the record establishes the Court's lack of jurisdiction, we will affirm.

BACKGROUND

Thousands of plaintiffs nationwide claim to have suffered injuries resulting from the surgical implantation of bone

1. 28 U.S.C. S 2680(a).

screws in their spines and have sued their doctors and the manufacturers of the screws; and, as is relevant here, some two hundred have also sued the federal government. These actions have been consolidated by the Judicial Panel on Multidistrict Litigation and transferred to the Eastern District of Pennsylvania as MDL No. 1014.²

1. Regulatory Process

It is undisputed that marketing of the bone screws is regulated by the Federal Food, Drug, and Cosmetic Act,³ as amended by the Medical Device Amendments of 1976 (MDA).⁴ At the time the lawsuits were filed, the FDA had classified the bone screws as Class III devices, a categorization reserved for devices presenting "a potential unreasonable risk of illness or injury."⁵ Before Class III devices can be marketed, they must receive "premarket approval" from the FDA⁶ or, alternatively, they must qualify for FDA clearance based on a substantial equivalence determination.⁷ It is a criminal offense to introduce a Class III medical device into commerce without approval or clearance.⁸

Because premarket approval is a lengthy, formal, and thus costly process often involving clinical trials under FDA supervision,⁹ most new Class III devices enter the market through FDA clearance.¹⁰ New Class III devices qualify for

2. The circumstances of this litigation have received more comprehensive attention elsewhere than is required in this appeal. See, e.g., *Buckman Co. v. Plaintiffs' Legal Comm.*, 121 S. Ct. 1012, 1015-16 (2001); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 784-87 (3d Cir. 1999).

3. Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-397).

4. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

5. 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

6. *Id.* § 360e(a).

7. *Id.* § 360e(b)(1); see also *Buckman*, 121 S. Ct. at 1015-16 (describing the FDA approval process applicable to the bone screw and similar devices).

8. See 21 U.S.C. § 331(a); *In re Orthopedic Bone Screw*, 193 F.3d at 786.

9. See generally 21 C.F.R. pt. 812.

10. See *Medtronic Inc. v. Lohr*, 518 U.S. 470, 479-80 (1996) (citing D. Kessler, S. Pape, & D. Sundwall, *The Federal Regulation of Medical Devices*, 317 *New England J. Med.* 357, 359 (1987)).

clearance when the FDA determines they are "substantially equivalent" to a legally marketed "predicate device" (usually a device that was marketed before the Medical Device Amendments went into effect on May 28, 1976).¹¹ The process by which this clearance is granted is known as the "S 510(k) process," in reference to the relevant MDA section. The process requires submission of the following:

1. "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use,"
2. "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement,"
3. "[a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted," and
4. "[a]ny additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution."¹²

The FDA grants clearance through the S 510(k) process when the new device has the same intended use as the predicate device and the FDA determines that it possesses the same technological characteristics or is as safe and effective as the predicate device.¹³

11. 21 U.S.C. S 360e(b)(1)(B).

12. 21 C.F.R. S 807.87; see also Buckman, 121 S. Ct. at 1016.

13. See 21 U.S.C. S 360c(i)(1); 21 C.F.R. S 807.100(b). According to S 360c(i)(1), a device is "substantially equivalent" to a predicate device if it "has the same intended use as the predicate device" and if the FDA has found it:

(i) has the same technological characteristics as the predicate device, or

2. Appellants' Allegations

In 1984, Zimmer Inc. applied for S 510(k) clearance for the Edwards Sacral Screw Device. After two rejections and the submission of additional supporting information, Zimmer was ultimately granted clearance. Appellants allege that the reasons for the FDA's reversal of position are unknown, and that the clearance decision was erroneous because the evidence presented to the FDA revealed no predicate device substantially equivalent to the Edwards screw on the market. Following this determination, the FDA granted S 510(k) clearance to other bone screws. Appellants allege these applications were granted due to the erroneous clearance of the Edwards screw. Appellants also claim that the FDA granted clearance to Danek Medical to market the IFS/Luque Device for non-spinal use when it knew or should have known that the screw was intended solely for spinal use. They allege that Danek first described the screw as the "Interpedicular Segmental Fixation System" but changed its name to "Warsaw Orthopedic Bone Plates" and "Warsaw Orthopedic Cancellous Bone Screws" after its initial S 510(k) application was denied. Along with the name change, Danek removed all references to use of the device in the spine, describing its application as only for long or flat bones. The FDA then granted clearance. Appellants make similar complaints regarding the S 510(k) process for some of the other screws. And furthermore, they allege that an FDA official proposed the idea of changing the intended use of the screws in order to obtain clearance and provided advice on circumventing FDA rules.

Appellants claim that the FDA's conduct in granting

(ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

clearance for each of the screws was negligent, intentionally erroneous,¹⁴ and in violation of its own policy. They further contend that this misconduct resulted in the marketing and subsequent use of the bone screws that ultimately injured them. The government argues that the discretionary function exception to the FTCA precludes Appellants' claims, regardless of their merit.

DISCUSSION

a.

Appellants first seek to get around the discretionary function exception by arguing that, because they have alleged that the FDA's conduct in clearing bone screws for the market was intentionally erroneous, and possibly even criminal, the exception is not applicable at all. In the Appellants' submission, the discretionary function exception was never intended to shield a government agency from liability for such dishonest and criminal conduct, and thus Appellants should be permitted to pursue their claims of intentional and criminal misconduct against the FDA without having to overcome the discretionary function bar. We are constrained to disagree.

Even prior to reaching the discretionary function exception issue, Appellants bear the burden of demonstrating that their claims fall within the scope of the FTCA's waiver of government immunity.¹⁵ Under the FTCA, the federal government only waives its immunity for injuries "caused by the negligent or wrongful act or omission of any employee of the Government . . . under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred."¹⁶ As the quoted language makes clear, the FTCA does not itself create a substantive cause of action against the United

14. Plaintiffs-Appellants accuse FDA officials of dishonest and even criminal conduct.

15. See *Cato v. United States*, 70 F.3d 1103, 1107 (9th Cir. 1995).

16. 28 U.S.C. S 1346(b)(1).

States; rather, it provides a mechanism for bringing a state law tort action against the federal government in federal court. Thus, "the extent of the United States' liability under the FTCA is generally determined by reference to state law."¹⁷

To state a viable FTCA claim based on their allegations of intentional and possibly criminal misconduct on the part of the FDA in the S 510(k) clearance process, Appellants need to demonstrate that such conduct amounted to a "negligent or wrongful act or omission" for which a private individual would be held liable under applicable state tort law. Appellants, however, face several hurdles to making this showing. First, we have examined the face of Appellants' complaints, and note that the complaints do not appear to allege that the FDA's behavior amounted to intentional or possibly criminal misconduct. Rather, in their complaints, Appellants contend that the FDA acted negligently and in violation of its own policies and procedures.¹⁸

Even if we were inclined to read Appellants' complaints liberally as stating claims based on the FDA's intentional and potentially criminal misconduct, we do not believe that these claims fall within the scope of the FTCA's sovereign

17. *Reo v. U.S. Postal Serv.*, 98 F.3d 73, 75 (3d Cir. 1996) (quoting *Molzof v. United States*, 502 U.S. 301, 305 (1992)) (internal quotation marks omitted).

18. In fact, even in their appellate briefing, Appellants continued to emphasize that the FDA's clearance decisions were wrongful because they were made negligently and in violation of the FDA's policies and procedures, and not because the FDA's behavior represented intentional misconduct or potentially criminal behavior. See Appellants' Opening Brief at 10 ("Plaintiffs allege that the FDA was negligent, careless, failed to exercise reasonable care and violated its own policy, practice and procedure with respect to substantial equivalence determinations in granting the requests by various manufacturers [for] 510(k) clearance."). Accordingly, the government's brief did not deal with this issue. Appellants did argue that the stay of discovery imposed by the District Court should be lifted because Appellants believed that they would obtain evidence of the FDA's intentional and possibly criminal misconduct, but it was not until oral argument on appeal that Appellants contended that their allegations regarding the FDA's intentional or criminal misbehavior should prevent any application of the discretionary function exception to Appellants' claims.

immunity waiver. Appellants have cast their allegations regarding the FDA's intentional misconduct and potentially criminal behavior only in generalized terms, and our treatment of these claims is, of necessity, similarly generalized. We do not believe that intentionally improper or even criminal behavior, in the abstract, constitutes the type of "negligent or wrongful act or omission" for which the FTCA grants a waiver of sovereign immunity.¹⁹ Appellants have not pointed us to (and we could find no) precedent standing for this general proposition, and, mindful of the fact that a government's waiver of its sovereign immunity must be construed narrowly,²⁰ we believe it is improper for us to conclude that Appellants' claims based on the FDA's allegedly intentionally dishonest and possibly criminal behavior fall within the scope of the FTCA's immunity waiver. Furthermore, to the extent that Appellants' claims have the state law analog necessary under the FTCA, we believe that the pertinent state cause of action is one for some type of intentional tort of fraud or deceit. Such intentional conduct, however, is explicitly exempted from the FTCA's waiver of sovereign immunity.²¹

b.

Appellants' claims do allege that the FDA acted negligently, and in violation of its own policies and procedures. This set of claims would fall within the FTCA's general waiver of sovereign immunity, and we must therefore determine whether the District Court's application of the discretionary function exception to these claims was correct.

19. We express no opinion on the question whether a specific set of factual allegations supporting the contention that a government agency acted in an intentionally wrongful or criminal manner could also support a contention that the government's behavior was "negligent or wrongful" within the meaning of the FTCA.

20. See *Clinton County Comm'rs v. EPA*, 116 F.3d 1018, 1021 (3d Cir. 1997) ("A waiver of immunity must be unequivocally expressed and is construed strictly in favor of the sovereign.") (internal quotation marks and citations omitted).

21. See 28 U.S.C. § 2680(h) (stating that the FTCA does not apply *inter alia* to "[a]ny claim arising out of . . . misrepresentation, deceit").

In *Berkovitz v. United States*,²² the Supreme Court held that the discretionary function exception applies when (1) the act involves "an element of judgment or choice" and (2) that discretion "is of the kind that the discretionary function exception was designed to shield."²³ This inquiry does not focus on anyone's subjective intent in the exercise of that discretion, however. Instead, the inquiry focuses on "the nature of the actions taken and on whether they are susceptible to policy analysis."²⁴

Appellants assert that both prongs of the *Berkovitz* inquiry support their position. They argue that the discretionary function exception does not apply to the S 510(k) clearances because (1) the FDA improperly granted the clearances, violating statutory and regulatory duties that do not allow for the exercise of any discretionary judgment or choice, and (2) the S 510(k) process involves merely scientific tasks rather than the exercise of policy-based discretion such as the exception was designed to protect. We disagree.

Under *Berkowitz*'s first prong, "[t]he requirement of judgment or choice is not satisfied if a 'federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow,' because 'the employee has no rightful option but to adhere to that directive.'"²⁵ FDA determinations concerning substantial equivalency are governed by 21 U.S.C. S 360c(i)(1) and 21 C.F.R. S 807.100(b), which explicitly grant the FDA discretion to require additional information "if deemed necessary" and to set standards for evaluation of safety and efficacy. Specifically, S 807.100(b) requires only (1) that the new device and the predicate device have the same intended use, (2) that the devices have the same technological characteristics or that data demonstrates the new device is as safe and effective as the predicate, and (3) that neither

22. 486 U.S. 531 (1988).

23. *Id.* at 536; see also *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997).

24. *United States v. Gaubert*, 499 U.S. 315, 325 (1991).

25. *Id.* at 322. (1991) (quoting *Berkowitz*, 486 U.S. at 536).

the Commissioner nor the courts have taken specific action against the new device.

Appellants contend that the FDA granted clearance for the screws even though it knew or should have known that screws had an altogether new intended use (namely, fixation to the vertebral pedicles of the spine), even though the screws had different technological characteristics, and even though the screws were not as safe or effective as the predicate devices. Appellants further allege that, by so doing, the FDA failed to perform the mandatory duties required by law for granting S 510(k) clearance, and thus did not exercise the judgment or choice necessary under Berkowitz's first prong to trigger the discretionary function exception.

The government argues that the statutory and regulatory provisions grant it discretion to decide what information is relevant in the S 510(k) process. Moreover, it points out that no mandatory authority dictates how it should go about determining whether devices have the same intended use, same technological characteristics, or similar performance in safety and efficacy. Accordingly, the government contends that the S 510(k) process requires the FDA to make discretionary choices utilizing its expertise. We agree.

When S 510(k) applications are brought before the FDA, regulators must decide what data and other information is relevant, what is reliable, and how much is sufficient. Certainly in weighing evidence and comparing medical devices in this manner, the FDA utilizes judgment and choice. Appellants' suggestion that the FDA violated statutory and regulatory provisions is, in reality, a claim that the FDA's judgment is wrong. Because substantial equivalence determinations as well as the manner in which those decisions get made are functions committed to the discretion of the FDA, we will not second guess their outcomes. The first step of the Berkovitz test is met.

Next, Appellants argue under the second Berkovitz prong that the S 510(k) process involves merely scientific tasks rather than the exercise of policy-based discretion. They rely on language in *Griffin v. United States*²⁶ for the

26. 500 F.2d 1059, 1066 (3d Cir. 1974).

proposition that scientific decisions do not fall within this exception. But their reliance is misplaced. Griffin concludes that some scientific determinations or measurements may not implicate policymaking discretion, not that science-based decisions never involve policymaking.²⁷ Because the S 510(k) process implicates such considerations as safety, efficacy, and cost, Griffin is not applicable. Furthermore, we have previously questioned the continuing authority of Griffin in light of subsequent Supreme Court decisions.²⁸

The FDA's regulatory judgment in the S 510(k) process is susceptible to policy analysis and therefore falls within the kind of discretion the exception is designed to protect. The S 510(k) process requires judgment regarding what evidence is relevant, how well that evidence demonstrates safety and efficacy, and what weight should be given conflicting evidence and opinions. Implicit in this judgment is the balancing of values such as safety and cost. Decisions made in this context reflect policy choices and cannot be categorized as ministerial. Thus the second step of the test is also met. The FDA's actions were protected by the discretionary function exception.

2. Stay of Discovery

The District Court stayed discovery in this case while it considered the government's motion to dismiss. Our standard of review of questions concerning the scope or opportunity for discovery is for abuse of discretion.²⁹ Appellants argue that the stay was improper and prevented them from uncovering evidence of wrongdoing by the FDA. But because Appellants' proposed discovery was aimed at supporting claims that, for the reasons stated in part 1.a, fall outside the FTCA, and because the District Court had

27. See *id.* ("At issue [is] a scientific, but not policy-making, determination as to whether each of the criteria listed in the regulation was met and the extent to which each such factor accurately indicated neurovirulence.").

28. See, e.g., *Smith v. Johns-Manville Corp.*, 795 F.2d 301, 309 (3rd. Cir. 1986).

29. See *Brumfield v. Sanders*, 232 F.3d 376, 380 (3rd. Cir. 2000).

no jurisdiction over these claims, it was appropriate to stay discovery. The District Court acted within its discretion.³⁰

The judgment of the District Court will be AFFIRMED.

A True Copy:

Teste:

Clerk of the United States Court of Appeals
for the Third Circuit

30. Cf. id.